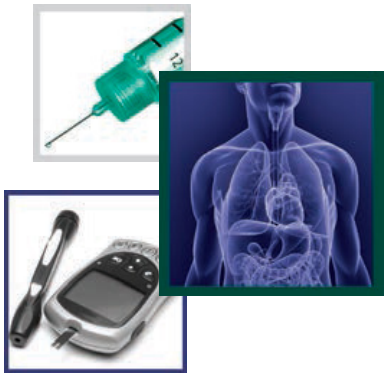

Does a holistic lifestyle intervention program improve health-related quality of life and psychological wellbeing in adults at diabetes risk?

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ABSTRACT

Background: While numerous studies have shown the beneficial effects of lifestyle intervention on clinical and laboratory parameters in persons at elevated diabetes and cardiovascular risk, research on the impact of lifestyle intervention on health-related quality of life and psychological wellbeing is scarce. Objectives: We examined the effect of a holistic 8-week long lifestyle intervention program compared to care-as-usual on health-related quality of life and psychological wellbeing in adults with diabetes and cardiovascular risk factors. Methods: We conducted a randomized controlled trial in a primary care setting in Hannover, Germany, with 83 participants who were either (pre) diabetic or at risk for diabetes (intervention group: n=43 aged (mean ± SD) 50.1 ± 6.1 years, control group: n=40 aged 53.3 ± 10.3 years). *CHIP Germany* is an 8-week coaching lifestyle intervention program including comprehensive nutritional and health education for primary and secondary prevention of diabetes and cardiovascular diseases. The primary outcome of the present analysis was health-related quality of life and psychological wellbeing after 12 months, assessed by the SF-12 and the W-BQ 22 Questionnaires, respectively. Results: After 12 months, in the intervention group no effect was seen on the SF-12 physical and mental component summary scores and the wellbeing-related scores, compared to controls. Small improvements in health-related quality of life and wellbeing were observed directly after the 8-week intervention; these changes, however, were not clinically relevant. Conclusion: For persons at diabetes and cardiovascular risk, the 8-week CHIP lifestyle intervention program showed small improvements on health-related quality of life and wellbeing only directly after the 8-week intervention period, but not 12 months after the intervention.

Introduction

Previous studies worldwide have shown the effectiveness of lifestyle intervention in reducing the risk of type 2 diabetes and cardiovascular diseases in overweight/obese, unhealthily nourished and physically inactive people [1-6]. While the beneficial effects of lifestyle intervention on clinical and laboratory parameters like body weight, Body Mass Index (BMI), blood pressure, blood glucose and blood lipids are well documented, less research has focused on the impact of lifestyle intervention on health-related quality of life and psychological wellbeing in persons at risk of developing type 2 diabetes [7].

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KEYWORDS

- diabetes prevention
- health-related quality of life
- psychological wellbeing
- randomized controlled trial

Objective

The objective of the study was to assess the benefits of the *CHIP* (Champion in Prevention) *Germany* program, a holistic 8-week long lifestyle intervention compared to care-as-usual in adults with (pre) diabetes and/or cardiovascular risk factors regarding health-related quality of life and psychological wellbeing after 12 months.

Methods

Design and recruitment

Details of the study design, the recruitment and randomization process and the methods involved in *CHIP Germany* have been published previously [8]. In brief, *CHIP Germany* is a comprehensive educational, multidisciplinary, intensive (40 h)-coaching lifestyle intervention program based on the American CHIP approach [9]. The German *CHIP* program focuses on weight reduction and the primary and secondary prevention of type 2 diabetes. The target population had either pre-diabetes, type 2 diabetes, was at risk of developing diabetes (i.e., a *FINDRISK* score >11 points) and/or had cardiovascular risk factors including overweight/obesity, arterial hypertension, elevated blood lipid-and/or glucose levels, unfavorable eating habits and physical inactivity. The 8-week lifestyle intervention was followed by a 10-month observational period. The program was designed as a randomized controlled trial in a primary care setting in Hannover and conducted for the first time in Germany. Participants were recruited through the German health insurance company Deutsche Angestellten-Krankenkasse (DAK). Out of 12,000 invited members, 127 showed interest in the study. Of these, 83 persons fulfilled at least one of the inclusion criteria, agreed to participate and were randomized to either the intervention (n=43) or the control group, i.e., waiting list (n=40) [8]. At study start, participants of the intervention group paid an "admission fee" of 75 Euros. Those who attended at least 12 of the 16 coaching sessions received a full refund from the health insurance company.

Lifestyle program *CHIP Germany* (*CHIP*)

During the 8-week lifestyle program participants of the intervention group were trained twice a week in sessions of 2.5 h each. The evening classroom presentations were held by a study physician and a nutritionist who took turns presenting information on epidemiological, clinical, nutritional and behavioral aspects of lifestyle-related chronic diseases [8]. The nutritional recommendations were based on a complex-carbohydrate-centered diet (65-70% of total daily calories). Participants were encouraged to embrace a whole food, plant-based diet "ad libitum" with emphasis on the consumption of whole-grains, legumes, fresh fruits and vegetables [5,6].

The *CHIP* intervention advocated exercise of moderate intensity for at least 30 min per day. Participants of the intervention group were encouraged to engage in any physical activity they enjoyed either as sports, recreational activities or incorporated into daily life activities. Workshops, like a dietitian-guided grocery shopping tour, cooking classes, and guided walking courses were offered on a voluntary basis [8]. The intervention incorporated the promotion of long-term health behavior changes, including social support, coping strategies and stress management techniques. During the follow-up period, monthly educational alumni-meetings were held providing group support and further information (e.g. on self-management techniques) contributing to the consolidation of new behavioral habits [8]. Participants of the control group received only "care-as-usual" by their general practitioners. They were also offered the possibility of joining a *CHIP* program after the end of the 12-month observation period. All study participants received a general health consultation and were given information on their blood tests and "Heart Screen" results, as described below [8].

Measures

"Heart Screen" (risk factor assessment)

To assess their individual levels of modifiable risk factors, all participants underwent blood testing for Fasting Plasma Glucose (FPG), blood lipids (total cholesterol, HDL and LDL cholesterol, triglycerides) and HbA1c (to assess blood glucose control reliably over time) at baseline, after the 8-week intervention and after 6 and 12 months [8]. Additionally, at the same time anthropometric (BMI, body weight, waist circumference) and vital parameters (Systolic (SBP) and Diastolic Blood Pressure (DBP)) were measured [8]. The diabetes risk score *FINDRISK* was applied as an additional screening instrument for the assessment of the long-term diabetes risk at baseline and after 12 months [8,10].

Questionnaires

At baseline and at all 3 follow-up time points, participants of both groups answered a detailed self-administered questionnaire addressing socio-demographics, medication use, level of physical activity, nutritional behavior and health beliefs. Health-related quality of life and psychological wellbeing were assessed by the standardized and validated questionnaires *"The Medical Outcomes Study Short-Form 12-Item Health Survey (SF-12)"* [11,12] and the *"Well-Being Questionnaire" (W-BQ 22)* [13]. All questionnaires were answered independently by the participants without physician interaction, mostly at home. The Well-Being Questionnaire was developed as a generic measure of several aspects of psychological wellbeing [14]. It discriminates between factors which are related to chronic illness and psychological status [13]. The W-BQ 22 consists of 22 items, scored on a Likert scale from 0-3, which were used for calculating the subscale scores of "depression", "anxiety", "energy", and "positive wellbeing" [15]. A higher value on the scale indicates an increase in the emotions described by the scale labels. An "overall wellbeing score" (W-BQ 22 total) is calculated by reversing the scores of negative items, summing the four subscale scores, and adjusting to achieve a scale maximum of 66 (overall well-being=36–depression–anxiety+positive wellbeing+energy) [15].

The SF-12 was used to assess the health-related quality of life. It was derived from *"The Medical Outcomes Study Short-Form Health Survey SF-36"* (SF-36) [16,17]. The SF-12, a brief comprehensive measure of perceived health status, includes 12 items selected from the SF-36: two items on physical functioning, two items on role physical, one item on bodily pain, one item on general health, one item on vitality, one item on social functioning, two items on role emotional, and two items on mental health [18]. The SF-12 was developed to provide a shorter but valid alternative version of the physical (PCS) and mental component summary scores (MCS) of the SF-36 [19]. Previous studies found the SF-12 to be an efficient alternative to the SF-36 for the assessment of health-related quality of life [20] with a high degree of correspondence between the physical and mental summary scores of both questionnaires [21]. SF-12 scores range from 0 to 100 with higher scores indicating a better health-related quality of life [20].

■ Data analysis and statistical methods

All data were analyzed as "Intent-to-Treat" (ITT). Therefore, missing data had to be imputed for persons who had prematurely discontinued the study or failed to answer the questionnaires at baseline and/or at follow-ups. Variables with incomplete baseline and follow-up data were completed by Multiple Imputation (MI). A total of 50 imputed data sets were used in the analysis [8,22]. Metric parameters were described by their Means (M) and Standard Deviations (SD). Discrete parameters were characterized by their frequency distributions and compared by means of the chi-square test; comparisons of dichotomous parameters were carried out using Fisher's exact test. In order to compare metric parameters between treatment and control group, a permutation based Augmented Mann-Whitney U test was applied [8,23]. The corresponding permutation null distributions were approximated using 10,000 random permutations, allowing sufficient accuracy of the estimated p-values [8,23]. The permutation based Augmented Mann-Whitney U test allows for flexible baseline covariate adjustment. The baseline values of the SF-12 physical and mental component summary scores and of the W-BQ 22 summary and subscale scores ("overall wellbeing", "depression", "anxiety", "positive wellbeing" and "energy") were used as covariates. All statistical tests used are nonparametric allowing for reliable analyses even if important requirements of parametric tests (e.g. normality) are not met or (as was the case here) cannot be reliably tested due to small sample sizes [8]. According to the study protocol, a 5% level of significance was applied.

Results

■ Socio-demographics and baseline characteristics

83 persons were enrolled and included in the ITT data analysis; n=43 (51.8%) and n=40 (48.2%) participants were randomized to the intervention and control group, respectively [8]. Participants were middle-aged, about 50% had a higher educational level (university entrance qualification or graduate degree), and the majority was female [8]. Oral antidiabetic medication was more frequently used in controls; the difference, however, did not reach statistical significance (p=0.228) [8].

At baseline, the body weight was (M ± SD) 87.3 ± 20.4 kg in the intervention group and

93.8 ± 16.4 kg in the control group (p=0.081), and the BMI was (M ± SD) 30.9 ± 6.4 kg/m² in the intervention group and 32.1 ± 6.0 kg/m² in controls, respectively (p=0.288). The fasting plasma glucose was (M ± SD) 86.6 ± 14.8 mg/dl in the intervention group and 95.8 ± 21.0 mg/dl in the control group (p=0.049), and the systolic blood pressure was (M ± SD) 149.2 ± 24.4 mmHg in the intervention group and 139.0 ± 16.1 mmHg in controls, respectively (p=0.055) [8]. For an in-depth description of additional anthropometric and laboratory parameters, the reader may refer to [8].

■ Drop-out and missing data

Details about drop-out rates and missingness patterns were reported previously [8]. In addition to the dropouts, a number of participants in both groups only partially answered or even completely failed to answer the questionnaires; in total, 69 complete questionnaires were available at baseline.

■ Program participation

All participants of the intervention group surpassed the minimum attendance threshold set at 75% and joined at least 12 of the 16 coaching sessions. More than 80% attended at least 14, and more than 40% attended all 16 coaching sessions. A majority joined the shopping tour and the cooking classes (75% and 90%, respectively), whereas only few persons attended the guided walking courses [8].

■ Changes in health-related quality of life and psychological wellbeing

Trends of the SF-12 physical (PCS-12) and mental component summary scores (MCS-12)

In the intervention group, small improvements in the SF-12 physical and mental component summary scores were seen directly after the 8-week intervention. These changes, however, were not clinically relevant. After 6 and 12 months no considerable differences were observed between the intervention and control group **(TABLE 1)**.

Trends of the wellbeing-related scores (W-BQ 22)

In the intervention group, there was a small non-clinically relevant trend towards improved "overall wellbeing" after 12 months, compared to controls. There were no considerable effects regarding the W-BQ 22 subscales "depression", "anxiety", "positive wellbeing" and " energy" at any of the 3 time points during the 12-month follow-up **(TABLE 2)**.

Discussion

■ Main findings

After 12 months, the intervention group did not differ from the control group regarding the primary outcomes, i.e., the SF-12 physical and mental component summary scores and the wellbeing-related scores. We observed only small non-clinically relevant improvements in health-related quality of life and wellbeing directly after the 8-week intervention **(TABLES 1 and 2)**.

■ Comparison with other studies and analyses

While our study showed no significant improvement in health-related quality of life and wellbeing, previously published lifestyle intervention studies found changes in at least one of the health-related quality of life components, i.e., either the perceived physical or mental health [7,24,25]. Several studies demonstrated

Table 1. Temporal development of physical (PCS-12) and mental (MCS-12) component summary score of the SF 12 (0=worst, 100=best).

Score	Time (months)	Intervention (n=43)		Control (n=40)		*p**
		M	SD	M	SD	
PCS-12	0	47.3	9.4	43.3	11.3	(0.128)
	2	49.1	7.8	43.7	9.2	(0.019)
	6	45.8	9.4	41.2	9.8	(0.115)
	12	47.9	7.8	43.4	7.8	0.038
MCS-12	0	46.7	11.7	45.3	9.4	(0.422)
	2	50.2	9.1	47.4	10.9	(0.330)
	6	48.0	8.5	47.7	8.9	(0.990)
	12	48.4	8.2	46.1	9.5	0.375

*p-values of the permutation based Augmented Mann-Whitney U test (adjusted for baseline differences of the respective parameter)
p-values in parentheses are subsidiary

Table 2. Temporal development of W-BQ 22 total and W-BQ 22 subscales.

Score	Time (months)	Intervention (n=43)		Control (n=40)		*p**
		M	*SD*	*M*	*SD*	
W-BQ total (points) from 0=worst to 66=best	0	43.9	10.2	42.1	10.4	(0.476)
	2	46.3	10.2	42.2	10.8	(0.102)
	6	45.9	9.2	43.9	8.4	(0.495)
	12	47.7	9.1	44.0	9.7	0.104
W-BQ depression (points) from 0=no depression to 18=worst depression	0	4.9	2.8	5.0	2.9	(0.717)
	2	4.5	2.9	5.2	3.1	(0.299)
	6	4.7	2.6	5.1	2.7	(0.671)
	12	4.1	2.6	5.0	2.9	0.158
W-BQ anxiety (points) from 0=no anxiety to 18=worst anxiety	0	6.3	3.4	6.8	3.5	(0.538)
	2	5.6	3.5	6.9	3.6	(0.073)
	6	5.7	3.2	6.3	3.0	(0.498)
	12	5.2	3.1	6.0	3.0	0.249
W-BQ energy (points) from 0=worst to 12=best	0	7.2	2.3	6.4	2.6	(0.214)
	2	7.8	2.1	6.7	2.7	(0.265)
	6	7.8	2.4	7.2	2.3	(0.561)
	12	8.0	2.1	7.4	2.3	0.542
W-BQ positive wellbeing (points) from 0=worst to 18=best	0	11.9	3.1	11.6	3.5	(0.669)
	2	12.6	3.1	11.6	3.2	(0.138)
	6	12.6	2.8	12.1	3.0	(0.510)
	12	12.9	3.1	11.6	3.5	0.145

*p-values of the permutation based Augmented Mann-Whitney U test (adjusted for baseline differences of the respective parameter)
p-values in parentheses are subsidiary

a positive effect of lifestyle intervention on even both perceived physical and mental health: Pisinger *et al.* found an association between increased physical activity at five-year follow-up and improvements in perceived physical health, assessed by the SF-12. Improvements in mental health were associated with a healthier diet at five-year follow-up than at baseline [26,27]. In contrast to our study the observation period was longer and the sample size larger. However, as in our study, participants were recruited from the general population. They were generally in good health already at baseline, which could have made improvements in health-related quality of life more difficult to achieve. It is therefore noteworthy that participants of the intervention group—in contrast to our study—were able to improve both physical and mental health.

Similarly, the American CHIP program showed beneficial effects on wellbeing, physical and psychological health in persons with elevated chronic disease risk factors: Participants of the intervention groups showed significantly greater increases in physical and mental health scores, compared to controls. These findings were partially mediated by the decrease in body weight [28-30].

In 2008, 182 persons with a cardio-metabolic risk profile comparable to our study population (middle-aged adults, mean BMI 31.5 ± 5.3 kg/m^2, mean fasting glucose 106 mg/dl) participated in the German lifestyle modification program "Prevention of Diabetes Self-Management" PREDIAS [7,31]. In the intervention group the SF-36 mental component summary score improved significantly after 12 months, whereas improvements in the SF-36 physical component summary score failed to reach statistical significance [7]. It is noteworthy that participants of the PREDIAS intervention group significantly increased their physical activity after 12 months, although they were only provided with information without—as it was the case in our study—being given the opportunity to participate in guided sport lessons. The increase in physical activity may have contributed to the mental health improvement in these persons. PREDIAS was less time-consuming than the German *CHIP* intervention (18 h vs. 40 h coaching program) and participants had potentially more time for physical activity. Furthermore, the PREDIAS teaching groups were smaller (7 vs. 43 participants), which could have made the lifestyle intervention more effective for the individual.

Studies evaluating the impact of lifestyle intervention on health-related quality of life and wellbeing thus yield inconsistent results. One reason for the different findings might be the heterogeneity regarding the presence of overweight/obesity in combination with other pre-existing chronic diseases among the study participants [32]: The coexistence of obesity and psychological or somatic illness was linked to a worsening of the physical and mental wellbeing [32,33]. In those persons, however, lifestyle intervention may improve health-related quality of life and wellbeing to a greater extent than in persons who are only overweight or obese. Furthermore, previous studies used different measures for the assessment of perceived physical and mental health, which affects the comparability of study results.

The German *CHIP* intervention was found to be effective in reducing body weight and several other cardiovascular risk factors like blood pressure, fasting glucose and blood lipids as well as improving the diabetes risk score *FINDRISK* after 12 months [8]. No effect, however, was seen on health-related quality of life and wellbeing. These findings might be due to the fact that an individual's perception and appraisal of the own health status and health-related quality of life are highly subjective and influenced by multidimensional factors. Psychosocial outcomes like health-related quality of life and wellbeing, therefore, might be more difficult to modify/improve and to assess than anthropometric and laboratory parameters. Moreover, when investigating psychosocial outcomes, researchers rely on self-report measures which, in turn, could make it more difficult to objectify these outcomes.

Although participants of the intervention group achieved a mean sustained weight loss of 4.1 kg after 12 months as published previously [8], they failed to significantly increase their physical activity. Although planning to increase physical activity, they were unable to translate intention into action [34]. This might explain the lack of improvements in health-related quality of life and wellbeing after 12 months in the intervention group. Moderate regular exercise can improve mental wellbeing and should be considered as a viable means of preventing or treating depression and anxiety [35,36]. The German *CHIP* program, however, focused more on improved nutrition than on physical activity. Thus, future lifestyle programs should include longer periods of intervention and incorporate physical activity much stronger into the individual lifestyle coaching in order to achieve synergistic effects on participants' health-related quality of life and psychological wellbeing. Although participants of both groups were at elevated metabolic and cardiovascular risk, they were generally in good health and did not suffer from serious limiting chronic diseases [8]. At baseline, participants of both groups had on average fairly good scores on the SF-12 and the Well-Being Questionnaires. Thus, with regard to these parameters, further improvement as a result of the intervention might have been more difficult to achieve. Participation in a lifestyle intervention study requires a certain level of motivation and, in turn, the absence of severe depressive symptoms and anxiety. Demonstrating their readiness to improve their health and to assume more personal responsibility for behavioral adjustments [37], it is conceivable that our participants were in a positive affective state already at study start, which may have affected the baseline mental health scores.

■ Limitations

One of the potential limitations in our study is related to missing data: In addition to the dropouts, a number of participants of both groups only partially answered or even completely failed to answer the questionnaires. Due to the number and length of the questionnaires in several follow-up examinations some participants may have lost interest and motivation over time. In our analyses we tried to compensate for missing data by applying multiple imputations, a recommended sophisticated technique [22,38].

Given the low response to participate in our intervention study we assume that our study population included particularly persons whose motivation and interest in the topic was above average, and that our study population cannot be considered as representative for the target population, i.e., all members of the DAK health insurance company [8]. Furthermore, about 50 percent of the participants had a high educational level [8] and, therefore, were not representative for an average risk population in Germany.

Although we included women and men in our study, there were only 7 men in the intervention and 13 men in the control group. Therefore, we did not conduct sex-specific subgroup analyses considering the lack of statistical power for the male subgroup.

Conclusion

The German *CHIP* program's impact on health-related quality of life and wellbeing was marginal: in the intervention group, improvements were either solely observed in the short-term directly after the 8-week intervention period or were not clinically relevant and small at the end of the 12-month observation period. This may have been due to the failure to substantially increase physical activity [34] and that the study participants were at relatively good health, which could have made a further improvement in health-related quality of life and wellbeing more difficult to achieve.

It is conceivable that anthropometric and laboratory parameters may be easier to modify in the short-term than subjective psychosocial outcomes like health-related quality of life and wellbeing, which are influenced by multidimensional factors. Therefore, future *CHIP* lifestyle programs should involve longer periods of intervention in order to facilitate positive effects on health-related quality of life and wellbeing. In view of the presumption that increased physical activity is positively related to improved physical and mental health, future *CHIP* programs should incorporate exercise much more into the individual lifestyle intervention.

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Conflict of interest

Heike Englert: project leader *CHIP Germany*. Klas Mildenstein: German adaptation of the American CHIP material, design and management of the *CHIP Germany* lifestyle intervention. Katharina Wennehorst: participation in the design of *CHIP Germany* and assistance during the intervention and follow-ups, responsible for participant management and data collection, data analysis and interpretation, and drafting of the manuscript. Brunhild Saliger: participation in participant management and data collection, assistance during the intervention and follow-up intervals. Heike Englert, Klas Mildenstein, Katharina Wennehorst, and Brunhild Saliger declare no conflict of interest. Thomas Keil: declares no conflict of interest regarding the *CHIP* program; he participated in the supervision of the statistical analyses, the critical appraisal of the study design, interpretation of the results, and in the writing of the manuscript.

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